IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

JIM NOVOTNEY,	)	
	)	
Plaintiff,	)	
	)	**No. 22 C 3439**
v.	)	
	)	**Judge Jorge L. Alonso**
WALGREEN CO.,	)	
	)	
Defendants.	)	

ORDER

Defendant Walgreen Co.'s motion to dismiss [15] is granted. This case is dismissed with prejudice.

STATEMENT

Plaintiff, Jim Novotney, brings this putative class action against defendant, the Walgreen Co., asserting state-law claims of fraud, breach of warranty, negligent misrepresentation and unjust enrichment. The Court has subject matter jurisdiction under the Class Action Fairness Act, 28 U.S.C. § 1332(d)(2).

Plaintiff's claims are rooted in defendant's practice of selling 3% hydrogen peroxide solution while representing that it is a "first aid antiseptic" to be used for "treatment of minor cuts and abrasions." In fact, plaintiff claims, hydrogen peroxide is ineffective in treating minor cuts and abrasions because, contrary to popular belief, it does not reduce rates of wound infection. While hydrogen peroxide may kill some potentially harmful bacteria, plaintiff claims, it does more harm than good because it also destroys beneficial bacteria and healthy cells that promote healing.

Defendant moves to dismiss under Federal Rule of Civil Procedure 12(b)(6), arguing that plaintiff's claims are preempted and he fails to plead sufficient facts to meet his pleading burden.

For the following reasons, the Court agrees that dismissal is appropriate because plaintiff's claims are preempted.

I. Applicable Law

"A motion under Rule 12(b)(6) tests whether the complaint states a claim on which relief may be granted." *Richards v. Mitcheff*, 696 F.3d 635, 637 (7th Cir. 2012). Under Rule 8(a)(2), a complaint must include "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). The short and plain statement under Rule 8(a)(2) must "'give the defendant fair notice of what . . . the claim is and the grounds upon which it rests.'" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). Under federal notice-pleading standards, a plaintiff's "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Id*. Stated differently, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id*. (citing *Twombly*, 550 U.S. at 556).

A. Preemption

"The preemption doctrine is grounded in the Constitution's Supremacy Clause." *Wis. Cent., Ltd. v. Shannon*, 539 F.3d 751, 762 (7th Cir. 2008). The Supremacy Clause declares that federal law "shall be the supreme Law of the Land . . . any Thing in the Constitution or Law of any State to the Contrary notwithstanding." U.S. Const. Art. VI., cl. 2. "Where state and federal law directly conflict, state law must give way." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617 (2011) (internal quotation marks omitted).

"Preemption is an affirmative defense, and pleadings need not anticipate or attempt to circumvent affirmative defenses." *Bausch v. Stryker Corp.*, 630 F.3d 546, 561 (7th Cir. 2010) (internal citation omitted). The preferred procedure for raising a preemption defense is to assert it in the answer and move for judgment on the pleadings under Federal Rule of Civil Procedure 12(c), rather than raising the issue in a motion to dismiss. *Id.*; *see Benson v. Fannie May Confections Brands, Inc.*, 944 F.3d 639, 645 (7th Cir. 2019). But granting a Rule 12(b)(6) motion to dismiss based on an affirmative defense such as preemption is "appropriate . . . 'where the allegations of the complaint itself set forth everything necessary to satisfy the affirmative defense.'" *Sidney Hillman Health Ctr. of Rochester v. Abbott Lab'ys, Inc.*, 782 F.3d 922, 928 (7th Cir. 2015) (quoting *Chicago Bldg. Design, P.C. v. Mongolian House, Inc.*, 770 F.3d 610, 614 (7th Cir. 2014)). If the plaintiff affirmatively pleads himself out of court by presenting "all relevant facts," *Brownmark Films, LLC v. Comedy Partners*, 682 F.3d 687, 690 (7th Cir. 2012), such that he has essentially "admit[ted] all the ingredients of an impenetrable defense," *Xechem, Inc. v. Bristol-Myers Squibb Co.*, 372 F.3d 899, 901 (7th Cir. 2004), then the Court need not insist that the defendant prepare and file two documents (an answer and a Rule 12(c) motion) where a Rule 12(b)(6) motion alone would do just as well. *See Wardingley v. Ecovyst Catalyst Techs., LLC*, No. 2:22-CV-115-PPS-JEM, 2022 WL 16714139, at *2 (N.D. Ind. Nov. 4, 2022) (analyzing preemption issue raised in Rule 12(b)(6) motion to dismiss because the Court had before it "all that is 'needed in order to . . . rule on the defense'") (quoting *Carr v. Tillery*, 591 F.3d 909, 913 (7th Cir. 2010)).

"Preemption can take on three different forms: express preemption, field preemption, and conflict preemption." *Aux Sable Liquid Prod. v. Murphy*, 526 F.3d 1028, 1033 (7th Cir. 2008). This case concerns express preemption, which is when Congress "define[s] explicitly the extent to which its enactments pre-empt state law." *English v. Gen. Elec. Co.*, 496 U.S. 72, 78 (1990).

B. Federal Law Governing Content of Over-The-Counter Drug Labels

The Food, Drug, and Cosmetics Act ("FDCA") regulates the marketing and labeling of drugs. *See* 21 U.S.C. § 301 *et seq*. The FDCA provides that no state may "establish . . . any requirement . . . that is different from or in addition to, or that is otherwise not identical with, a requirement" of the FDCA. 21 U.S.C. § 379r(a).

The Secretary of Health and Human Services has "authority to promulgate regulations for the efficient enforcement" of the FDCA, 21 U.S.C.A. § 371(a), which he accomplishes through the Food and Drug Administration ("FDA") and its Commissioner, 21 U.S.C. § 393(a), (b), (d)(2). Drug manufacturers must apply to the FDA for approval before marketing their products, so that the FDA may determine whether the drugs are safe and effective for use as labeled. 21 U.S.C. § 355(a), (b), (j); *see Wyeth v. Levine*, 555 U.S. 555, 566 (2009).

The FDA regulates over-the-counter ("OTC") drugs via its "Over the Counter Drug Review" process, which the Second Circuit has described as follows:

> Commenced in 1972, the OTC Drug Review established FDA's "monograph" system for regulating over-the-counter drugs. *See* 21 C.F.R. § 330.10; 37 Fed. Reg. 9464 (May 11, 1972). While FDA must [typically] approve drugs as [generally recognized as safe and effective ("GRAS/E")] individually, the monograph system allows manufacturers to bypass individualized review. *See* 21 U.S.C. § 355; 21 C.F.R. § 330.10. Under this system, FDA issues a detailed regulation—a "monograph"—for each therapeutic class of OTC drug products. Like a recipe, each monograph sets out the FDA-approved active ingredients for a given therapeutic class of OTC drugs and provides the conditions under which each active ingredient is GRAS/E.

NRDC v. FDA, 710 F.3d 71, 75 (2d Cir. 2013); *see In re Tylenol (Acetaminophen) Mktg., Sales Practices & Prod. Liab. Litig.*, 144 F. Supp. 3d 699, 708-11 (E.D. Pa. 2015) (describing the "monograph system" as "essentially an expanded version of administrative notice-and-comment rulemaking" for drugs with active ingredients in longtime use).

The FDA regulates 3% hydrogen peroxide solution for antiseptic use under a 1991 "tentative final monograph," *Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for First Aid Antiseptic Drug Products*, 56 Fed. Reg. 33644 (July 22, 1991) ("1991 TFM"); *see* 21 C.F.R. § 330.10(a)(7)(i) ("After reviewing all comments, reply comments, and any new data and information or, alternatively, after reviewing a panel's recommendations, the Commissioner shall publish in the Federal Register a tentative order containing a monograph establishing conditions under which a category of OTC drugs or specific OTC drugs are generally recognized as safe and effective and not misbranded."). The 1991 TFM became final under the Coronavirus Aid, Relief and Economic Security Act in 2020. *See* 21 U.S.C. § 355h(b)(8)(A). The monograph states as follows, in pertinent part:

> The submission forwarded by the manufacturer (Ref. 3) included labeling for a currently marketed product containing hydrogen peroxide solution U.S.P. 3 percent, which states: "First aid antiseptic" "For treatment of minor cuts and abrasions." The submission also included safety and effectiveness data from published articles and unpublished studies. These data indicate that hydrogen peroxide inhibits S. aureus, Salmonella typhosa, Escherichia coli (E. coli), Proteus vulgaris, Klebsiella pneumoniae, Streptococcus hemolyticus, and P. aeruqinosa. The manufacturer also provided in vitro data to show that 3 percent hydrogen peroxide reduced the number of S. aureus ATCC 6538P by 3 logs (3 log10) within 5 minutes and completely inhibited all bacteria within 10 minutes.
>
> In a separate OTC drug rulemaking, for OTC oral mucosal injury drug products, the agency found hydrogen peroxide (3 percent in aqueous solution) safe for short-term use up to 7 days. (See the Federal Register of July 26, 1983, 48 FR 33984 at 33993.)
>
> Hydrogen peroxide achieves its intended benefit in vivo by means of both a mechanical action and a measurable antibacterial action. Because hydrogen peroxide has been demonstrated to be both safe and effective for use in minor wounds, the agency is proposing to classify hydrogen peroxide (3 percent in aqueous solution) as Category I for use as a first aid antiseptic drug product.

1991 TFM, 56 Fed. Reg. at 33659.

II. Discussion

Defendant argues that dismissal is appropriate because the language that plaintiff challenges on defendant's product label closely tracks language in the labeling of the hydrogen peroxide product that the FDA considered in the now-final 1991 TFM. According to defendant, any state law that would require defendant's label to say something else in order to properly inform consumers about the use and effectiveness of the product would impose a requirement that is "not identical" to federal law.

In response, plaintiff makes three arguments. The Court is not persuaded by any of them. In fact, following briefing of the present motion to dismiss, another court in this district issued an order dismissing a complaint similar to plaintiff's. In that decision, the Court rejected a number of the same arguments plaintiff makes here. *See Abron v. Vi-Jon, LLC*, Case No. 22 C 50238 (N.D. Ill. Jun. 20, 2023). The Court finds that decision persuasive, and it rejects plaintiff's arguments for similar reasons.

First, plaintiff argues that he is not "attempting to impose requirements 'different from' or 'in addition to' federal requirements, because the representations about the product's efficacy were made to him, not to the FDA." (Pl.'s Mem. in Opp. At 7, ECF No. 21.) This seems to mischaracterize the federal-law requirement at issue, which is not about what the defendant or another drug manufacturer can say to the FDA about hydrogen peroxide; it is about how the product is to be labeled in relation to its intended use. The monograph provides that a 3% hydrogen peroxide solution labeled as a "first aid antiseptic" used "for treatment of minor cuts and abrasions" has been demonstrated to be "safe and effective for use in minor wounds . . . as a first aid antiseptic." The gravamen of plaintiff's claims is that this very labeling, which is regulated by the FDA, is misleading because hydrogen peroxide is *not* effective as a first aid antiseptic for treatment

of minor cuts and abrasions. Because plaintiff's claims require him to establish, in essence, that state law imposes labeling requirements on defendant that are different from, additional to, or otherwise not identical with, requirements of federal law, his claims are preempted. *See Abron* at 3 ("[P]laintiff is complaining about the label. The FDA regulates the content of the label to control information that the label conveys to consumers like plaintiff. . . . Plaintiff's argument is baseless.").

Second, plaintiff cites statements in two other OTC monographs that plaintiff interprets as supporting his claim that hydrogen peroxide solution is not effective to treat minor wounds. First, in a 1977 monograph about topical antibiotics, the FDA stated that the scientific evidence then available did not "sufficiently answer the question of the role of bacteria in minor skin wounds," and there was "little evidence to support the claims that reduction of the number of bacteria in wounds will shorten dermal and epithelial healing times." *Over The Counter Drugs; Establishment of a Monograph for OTC Topical Antibiotic Products*, 42 Fed. Reg. 17642, 17648 (Apr. 1, 1977). Second, in a 1982 monograph about oral health care drug products, the FDA stated that certain antimicrobial agents, including hydrogen peroxide, were "not only ineffective but may also retard the healing of clean or infected wounds," and it was "difficult to imagine circumstances whereby hydrogen peroxide kills bacteria, but is not injurious to tissue." *Oral Health Care Drug Products for Over-the-Counter Human Use; Establishment of a Monograph*, 47 Fed. Reg. 22760, 22831, 22876 (May 25, 1982).

In context, however, these statements are irrelevant to the use of hydrogen peroxide as a "first aid antiseptic for treatment of minor cuts and abrasions." *See Abron* at 3-4 (rejecting a similar argument because "the cited material is inapposite"). The 1977 monograph addressed topical antibiotics, not antiseptics, and it did not mention hydrogen peroxide. The 1982 monograph

addressed the effective use—or lack thereof—of hydrogen peroxide as an *oral* "antimicrobial agent," not as a topical antiseptic. *See* 42 Fed. Reg. at 22876 ("The Panel concludes that there are insufficient data available to permit final classification of the effectiveness of hydrogen peroxide as an OTC antimicrobial agent for topical use *on the mucous membranes of the mouth and throat*."); *id.* ("The Panel concludes that there are insufficient data from controlled studies to establish the effectiveness of hydrogen peroxide as an antimicrobial agent for the treatment of symptoms such as sore mouth and sore throat."). These statements simply have nothing to do with the labeling of hydrogen peroxide solution for use as a "first aid antiseptic for treatment of minor cuts and abrasions." The 1991 TFM contains the relevant statements on the relevant use of hydrogen peroxide, and those statements point in a different direction. Because the 1991 TFM provides that hydrogen peroxide is an effective first aid antiseptic for minor cuts and abrasions, and labeling hydrogen peroxide as such meets with the approval of federal law, plaintiff's claims are preempted to the extent that they depend on demonstrating that state law does *not* permit such labeling.

Third, plaintiff argues that, even focusing narrowly on the 1991 TFM, the FDA did not specifically approve the use of the word "treatment" in connection with hydrogen peroxide. Instead, plaintiff argues, it described the "indication" for "first aid antiseptics" as follows: "'First aid to help' [select one of the following: 'prevent,' ('decrease' ('the risk of" or 'the chance of')), ('reduce' ('the risk of' or 'the chance of')), 'guard against,' or 'protect against'] [select one of the following: 'infection,' 'bacterial contamination,' or 'skin infection'] 'in minor cuts, scrapes, and burns." 56 Fed. Reg. at 33650; *see also id.* ("Therefore, the agency is proposing in this amended tentative final monograph to define the term "first aid antiseptic" as follows: "An antiseptic-containing drug product applied topically to the skin to help prevent infection in minor cuts,

scrapes, and burns."). The 1991 TFM also stated, "Manufacturers choosing to market a first aid product with this claim need only meet the requirements specified in the proposed monograph." *Id.* The word "treatment" does not appear in this "new indication," and therefore, plaintiff argues, it is outside the scope of language that the FDA approved in connection with hydrogen peroxide. Under plaintiff's logic, then, asserting that the use of the word "treatment" on the product's label is misleading is not imposing a requirement that is different from, additional to, or otherwise not identical with, a requirement of the FDCA.

But the Court agrees with defendant that whether the FDA specifically approved the use of the word "treatment" is beside the point. The content of the product's label as it relates to its safety or effectiveness is a matter of federal law, and by claiming that some other terminology is necessary to ensure that the label is not misleading, plaintiff impermissibly claims that state law imposes requirements that are different from, additional to, or otherwise not identical with, the requirements of the FDCA. *See Turek v. Gen. Mills, Inc.*, 662 F.3d 423, 427 (7th Cir. 2011) (explaining that similar claims about whether a label was misleading in stating the product's percentage daily value of fiber were preempted because, if successful, they would require the addition of "disclaimers" that were "not identical to the labeling requirements imposed on such products by federal law").[1] And a de minimis difference between the wording of the label and wording in a monograph does not save the claim, if it is clear that the label in question complies with federal standards by "advertis[ing] . . . accurate[ly]" the uses for which the product has been

[1] Plaintiff purports to distinguish *Turek* by citing its reliance on a Department of Agriculture regulation, 7 C.F.R. § 205.606(m), but the Seventh Circuit cited that regulation only by way of demonstrating that neither that regulation nor any other federal regulation requires disclaimers about inulin (the kind of fiber in the product at issue) of the sort that the plaintiff claimed that the label required. *Turek*, 662 F.3d at 427. Therefore, the citation to this regulation in no way weakens the applicability of the reasoning of *Turek* to this case.

approved as safe and effective. *See Sapienza v. Albertson's Cos., Inc.*, No. CV 22-10968-RGS, 2022 WL 17404919, at *3 (D. Mass. Dec. 2, 2022); *see also id.* at 3 ("FDA preemption regulates [the relevant] standards generally – the subject matter of [the plaintiff's] state-law claims – even if the wordings slightly differ." (citing cases)). The legislative history of the preemption provision at issue supports this "commonsense interpretation." *Id.* (citing S. Rep. No. 105-43, at 64 (1997) ("No State or local government is permitted to impose different or additional requirements that *relate to the subject matter* covered by the three Federal laws as they apply to nonprescription drugs and cosmetics. These include requirements imposed on product manufacture or composition, *labeling*, advertising, or any other form of public notification or communication.") (emphasis added).

For all these reasons, the Court agrees with defendant that plaintiff's claims are preempted. The Court need not reach defendant's arguments about whether plaintiff has met his pleading burden by pleading sufficient factual matter to state a claim. Typically, the Court gives plaintiffs whose complaints do not survive a motion to dismiss a chance to amend their complaints at least once. But here, "amendment would be futile because no amended complaint can change the fact [that] plaintiff's claim is preempted under 21 U.S.C. § 379(a)(2)." *Abron* at 7. Defendant's motion to dismiss is granted, and this case is closed.

SO ORDERED.

ENTERED: July 20, 2023

HON. JORGE ALONSO
United States District Judge